*Foreign exchange fluctuations may adversely affect our earnings and the value of our non-Swiss assets*

We record our transactions and prepare our financial statements in Swiss francs, but a significant portion of our earnings and expenditures are in other currencies. In 2001, 45% of our sales were made in US dollars, 23% in Euro, 8% in Japanese yen, 5% in Swiss francs and 19% in other currencies. 31% of our costs were generated in US dollars, 26% in Swiss francs, 22% in Euro, 5% in Japanese yen and 16% in other currencies. Changes in exchange rates between the Swiss franc and these other currencies can result in increases or decreases in our costs and earnings. Fluctuations in exchange rates between the Swiss franc and other currencies may also affect the book value of our assets outside Switzerland and the amount of shareholders' equity. We seek to minimize our currency exposure by engaging in hedging transactions, where we deem it appropriate. To mitigate some of these risks, we have hedged certain US dollar and Japanese yen positions for 2002. We cannot predict, however, all changes in currency and interest rates, inflation or other factors, which could affect our international businesses.

## Item 4. Information on the Company

### 4.A History and Development of Novartis

Novartis AG, headquartered in Basel, Switzerland, is a public company incorporated under the laws of Switzerland with an indefinite duration. We were created as a result of the merger of Sandoz AG and CIBA-Geigy AG (the "Merger") in December 1996. Prior to the Merger, Sandoz AG and CIBA-Geigy AG were each global participants in the pharmaceutical and agrochemical industries. We are domiciled in and are governed by the laws of Switzerland.

Our Group companies employ approximately 71,000 people worldwide and operate in over 140 countries. Our registered shares are listed in Switzerland on the SWX Swiss Exchange ("SWX") and traded on the European trading platform virt-x, and our American Depositary Shares are listed on the New York Stock Exchange ("NYSE"). Our registered office is located at Lichtstrasse 35, 4056 Basel and our telephone number is 011-41-61-324-1111. We maintain an Internet website at http://www.novartis.com.

*Major transactions in 2001, 2000 and 1999*

On May 5, 2001 we announced the acquisition of 32 million bearer shares of Roche Holdings Ltd, representing 20% of the voting shares of that company for approximately CHF 4.8 billion (approximately US$2.8 billion). These shares were purchased as a package from BZ Gruppe Holding and are intended as a financial investment of a potentially strategic nature. At December 31, 2001 we held 21.3% of the voting shares of Roche Holding Ltd, which represents an approximate 4% interest in the total Roche equity.

On December 21, 2000, Novartis Pharmaceuticals completed the acquisition of the antiviral products Famvir® (famciclovir) and Vectavir®/Denavir® (penciclovir) from SmithKline Beecham, for a total price of CHF 2.7 billion approximately (US $1.6 billion). We expect the acquisition of these products to expand our franchise in the primary care market.

In November 2000, we spun-off and merged our Crop Protection and Seeds businesses with AstraZeneca's Zeneca Agrochemicals to create Syngenta AG ("Syngenta"), which is headquartered in Basel, Switzerland, and is listed on the Swiss, London, New York and Stockholm stock exchanges.

On October 2, 2000, CIBA Vision acquired the stock of Wesley Jessen VisionCare Inc., a US corporation for CHF 1.3 billion (approximately $800 million) in cash.

For a description of our principal capital expenditures and divestitures, see "Item 5. Operating and Financial Review and Prospects—5.B. Liquidity and Capital Resources."

*General Corporate Initiatives*

We have undertaken a number of initiatives designed to make our management of the Group more transparent to investors and advance our corporate citizenship ideals.

In 2002:

- In the United States, we instituted the Novartis *CareCard*[sm] program to assist low income elderly to obtain the Novartis medications they need at significant discounts.

In 2001:

- A Board-level committee was created to develop and implement sound corporate governance principles;
- The Board's Audit Committee was given additional responsibility to monitor our compliance with law and policy;
- A new Policy of Corporate Citizenship was instituted which sets the framework for our commitment to making corporate citizenship an integral aspect of our business;
- A patient assistance program was created to help persons with limited financial means to afford Glivec®/Gleevec™, our innovative medication for chronic myeloid leukemia;
- In collaboration with the World Health Organization ("WHO"), we announced a plan to stem the spread of malaria in Africa and other endemic regions in the developing world. As part of a world-wide initiative entitled "Roll Back Malaria," we will provide specially designed packs of Coartem®, our novel malaria treatment, for distribution through WHO at cost;
- We established the Novartis Institute for Tropical Diseases in Singapore to target tropical diseases, including Dengue fever, and infections like tuberculosis;
- Our shares were split 40 for 1 so that there is now a 1:1 share-to-ADS ratio.

In 2000:

- The Novartis Code of Conduct was rolled out to our employees throughout the world;
- We were among the first companies to join the Global Compact, a multilateral initiative of United Nations Secretary General Kofi Annan that is consistent with our own approach to business ethics. The Global Compact formulates nine principles in the areas of environmental protection, respect for the workforce, and human rights.

In 1999:

- The Novartis Code of Conduct was approved;
- We pledged to donate approximately US$30 million in medication to cure all the leprosy patients in the world detected through 2005. This is our key contribution to the Global Alliance, associated with the WHO, that aims to eliminate leprosy as a public health problem from every country by the year 2005;

As part of our commitment to focus not just on our business, but on the business of being a responsible member of the global community, we implemented initiatives like the Novartis Community Partnership Day where all our employees are encouraged, for one day each year, to give time back to the communities in which we operate.

## 4.B Business Overview

### General

We are a world leader both in sales and in innovation in our continuing core business: pharmaceuticals, generics, consumer health, eyecare products, and animal health. We aim to hold a leadership position in all of these businesses. We are committed to improving health and well-being through innovative products and services. The name "Novartis" is derived from the Latin *novae artes*, meaning "new skills," which reflects our focus on research and development.

### Product Sectors and Geographic Markets

We currently operate in five principle industry sectors: Pharmaceuticals, Generics, Consumer Health, CIBA Vision, and Animal Health. All references to Group figures, unless otherwise indicated, including employees and sales, include the Agribusiness sector, up until the November 6, 2000 spin-off. The following tables set forth the Group's sales and operating income by business sector for the financial years ended December 31, 2001, 2000 and 1999.

| | Year ended December 31, | | | |
|---|---|---|---|---|
| | **2001** | **2000[1]** | **2000** | **1999** |
| | | (in CHF millions) | | |
| **Sales to third parties** | | | | |
| Pharmaceuticals | 20,181 | 18,150 | 17,611 | 15,275 |
| Generics | 2,433 | 1,973 | 1,938 | 1,823 |
| Consumer Health — ongoing | 6,675 | 6,514 | 6,395 | 5,570 |
| Divested Consumer Health activities | | | | 182 |
| CIBA Vision | 1,787 | 1,392 | 2,085 | 1,632 |
| Animal Health | 962 | 1,083 | 1,083 | 927 |
| **Sales of continuing activities** | **32,038** | **29,112** | **29,112** | **25,409** |
| Sales from discontinued Agribusiness activities[2] | | 6,693 | 6,693 | 7,056 |
| **Group sales** | **32,038** | **35,805** | **35,805** | **32,465** |
| **Operating income** | | | | |
| Pharmaceuticals | 5,677 | 5,401 | 5,403 | 4,676 |
| Generics | 281 | 242 | 227 | 347 |
| Consumer Health — ongoing | 920 | 869 | 824 | 807 |
| Divested Consumer Health activities | | | | 375 |
| CIBA Vision | 174 | 100 | 158 | 250 |
| Animal Health | 138 | 179 | 179 | 216 |
| Corporate and Other | 87 | (64) | (64) | 25 |
| **Operating income from continuing activities** | **7,277** | **6,727** | **6,727** | **6,696** |
| Operating income from discontinued Agribusiness activities[2] | | 1,156 | 1,156 | 647 |
| **Group operating income** | **7,277** | **7,883** | **7,883** | **7,343** |

(1) 2000 sector reporting has been restated to reflect the transfer as of January 1, 2001 of the Ophthalmics business from CIBA Vision to the Pharmaceuticals sector and the switch of certain products between sectors.

(2) Agribusiness: Crop Protection and Seeds businesses through November 6, 2000, the date of spin-off.

The table below sets forth a regional breakdown of certain data for the years ended December 31, 2001, 2000 and 1999.

| | Americas | | | Europe | | | Rest of the World | | |
|---|---|---|---|---|---|---|---|---|---|
| | 2001 | 2000 | 1999 | 2001 | 2000 | 1999 | 2001 | 2000 | 1999 |
| Sales (CHF m) | 16,640 | 17,761 | 15,328 | 10,158 | 11,729 | 11,620 | 5,240 | 6,315 | 5,517 |
| Operating income (CHF m) | 2,158 | 2,474 | 2,170 | 4,555 | 4,469 | 4,549 | 564 | 940 | 624 |
| Number of employees (at December 31) | 27,303 | 27,063 | 29,077 | 31,386 | 28,815 | 38,125 | 12,427 | 11,775 | 14,652 |
| Investment in tangible fixed assets (CHF m) | 723 | 475 | 510 | 560 | 790 | 754 | 68 | 88 | 107 |
| Depreciation of tangible fixed assets (CHF m) | (311) | (388) | (351) | (561) | (715) | (790) | (67) | (86) | (120) |
| Net operating assets (CHF m) | 10,590 | 9,774 | 7,780 | 15,759 | 11,176 | 14,936 | 1,722 | 1,529 | 2,043 |

**PHARMACEUTICALS**

The business of our Pharmaceuticals sector is conducted by a number of affiliated companies throughout the world. We are a world leader in the discovery, development, manufacture and marketing of prescription medicines. Our goal is to provide a broad portfolio of effective and safe products and services to patients through healthcare professionals around the world. This goal is supported by approximately 80 affiliates operating in more than 140 countries. In 2001, the affiliated companies of our Pharmaceuticals sector employed 41,256 people and had CHF 20,181 million in sales, which represented 63% of the Group's sales.

Our product portfolio includes a wide range of products in eight major disease areas: (i) cardiovascular/metabolism/endocrinology; (ii) oncology/hematology; (iii) central nervous system; (iv) transplantation/immunology; (v) dermatology; (vi) respiratory; (vii) rheumatology/bone/hormone replacement therapy ("HRT") and (viii) ophthalmics. Effective January 1, 2001, Novartis Pharmaceuticals took over responsibility for operating the ophthalmic pharmaceutical business previously managed by CIBA Vision. Our Pharmaceuticals sector is organized into five Business Units: Primary Care, Oncology, Transplantation, Ophthalmics and Mature Products. The Business Units coordinate the worldwide research, distribution, marketing and sales of the products assigned to each.

The current product portfolio includes 30 key marketed products, of which 4 were launched in 2001. In addition, the portfolio includes a further 66 projects in development. See "—Research and Development."

**Key Marketed Products**

The following table describes the key marketed products of our Pharmaceuticals sector.

| Therapeutic area | Project/ Compound | Generic name | Indication | Formulation |
|---|---|---|---|---|
| Cardiovascular, metabolism and endocrinology | Diovan® | valsartan | Hypertension | Capsule |
| | Co-Diovan® | valsartan + HCTZ | Hypertension | Film-coated tablet |
| | Lescol® | fluvastatin | Cholesterol-lowering agent | Capsule |
| | Lotrel® | benazepril & amlodipine | Hypertension | Capsule |
| | Cibacen®/ Lotensin® | benazepril | Hypertension | Coated tablet |
| | Cibadrex®/ Lotensin HCT® | benazepril + HCTZ | Hypertension | Coated tablet |
| | Starlix® | nateglinide | Type-2 diabetes | Tablet |
| | Zelmac®/ Zelnorm® | tegaserod/tegaserod maleate | Symptomatic treatment of Irritable Bowel Syndrome | Tablet |
| Oncology and hematology | Aredia® | pamidronate | Conditions associated with cancer | Intravenous infusion |
| | Femara® | letrozole | Advanced breast cancer | Coated tablet |
| | Glivec®/ Gleevec™ | imatinib | Chronic Myeloid Leukemia | Capsule |
| | | | Gastrointestinal Stromal Tumors | Capsule |
| | Sandostatin® LAR | octreotide | Acromegaly, cancer | Intramuscular injection |
| | Zometa® | zoledronic acid | Hypercalcaemia of malignancy | Infusion |
| | | | Bone metastases treatment | Infusion |
| Central nervous system | Exelon® | rivastigmine | Alzheimer's disease | Capsule |
| | Leponex®/ Clorazil® | clozapine | Antipsychotic agent for treatment-resistant schizophrenia | Tablet, ampoule |
| | Tegretol® | carbamazepine | Epilepsy, acute and bipolar affective disorders | Tablet, chewable tablet, syrup, suppository |
| | Trileptal® | oxcarbazepine | Epilepsy | Tablet, oral suspension |
| | Comtan® | entacapone | Parkinson's disease | Film-coated tablet |
| Transplantation | Neoral®/ Sandimmun® | cyclosporine | Prevention of graft rejection following organ and bone marrow transplantation | Soft gelatin capsule, oral solution, intravenous infusion |
| | Simulect® | basiliximab | Acute organ rejection in de novo renal transplantation | Intravenous infusion or injection |
| Dermatology | Elidel® | pimecrolimus cream | Eczema | Cream |
| | Famvir® | famciclovir | Acute herpes zoster | Tablet |
| | Lamisil® | terbinafine | Fungal infections of the skin and nails | Tablet, cream, *DermGel*, solution, spray |

| Therapeutic area | Project/ Compound | Generic name | Indication | Formulation |
|---|---|---|---|---|
| Respiratory | Foradil® | formoterol | Asthma, chronic obstructive pulmonary disease | Inhalation capsule (aerosol) |
| Rheuma, bone and hormone replacement therapy | Estalis® | estradiol norethisterone acetate | Postmenopausal symptoms and osteoporosis | Patch |
| | Estraderm® TTS/MX | estradiol | Estrogen deficiency following menopause | Patch |
| | Miacalcic® | salmon calcitonin | Osteoporosis, regulator of mineral homeostasis and skeletal metabolism | Nasal spray |
| | Voltaren® | diclofenac | Inflammatory forms of rheumatism, pain management | Enteric coated tablet, drop, ampoule |
| Ophthalmics | Visudyne® | verteporfin | Wet form of age-related macular degeneration | Intravenous infusion, activated by laser light |
| | Zaditen® | ketotifen | Ocular allergy | Drop |

Not all products are registered in all markets for the treatment areas described above.

**Compounds in Development**

The following table describes our most important compounds presently under development. "Filed" means either filed with the Food and Drug Administration of the United States ("FDA"), in the European Union (by either centralized or mutual recognition procedure), and/or with national health authorities, but not necessarily in all jurisdictions.

| Therapeutic area | Project/ Compound | Generic name | Indication | Estimated Filing Date/Phase[1] |
|---|---|---|---|---|
| Cardiovascular, metabolism and endocrinology | SPP100[2] | — | Hypertension | 2004/II |
| | LAF237 | — | Type-II diabetes | 2004/II |
| | Zelmac®/ Zelnorm® | tegaserod | Functional dyspepsia | 2003/II |
| | | | Gastroesophagal reflux disease | 2005/II |
| | | | Chronic constipation | 2003/III |
| | | | Irritable bowel syndrome | 2003/III |
| | Diovan® | valsartan | Congestive heart failure | Filed |
| | | | Post-and pre-myocardial infarction | 2004/III |
| | Sandostatin® LAR | octreotide acetate | Diabetic retinopathy, other indications | 2004/III |
| | Lotrel® 10-20 | amlodipine+ benazepril | Hypertension | Filed (United States) |
| | Lotrel® 10-40 | amlodipine+ benazepril | Hypertension | 2002 (United States)/III |
| | NKS104 | pitavastatin | Dyslipidemia | 2005 (EU)/II |
| | Starlix®/ metformin | — | Type-II diabetes | 2004 II |
| | Starlix®/ Diovan® | (Navigator Trial) | Prevention of onset of Type II diabetes | >2005 III |

(1) Phase II: Clinical trials in patients to determine dose ranging, safety and efficacy. Phase III: Large clinical trials to determine definitive safety and efficacy in patients.

(2) This compound was out-licensed to Speedel with a callback option.

| Therapeutic area | Project/ Compound | Generic name | Indication | Estimated Filing Date/Phase[1] |
|---|---|---|---|---|
| Oncology and hematology | Glivec®/ Gleevec™ | imatinib mesylate | GIST (gastrointestinal stromal tumors) | US approved/EU Filed |
| | | — | Solid tumors | Filing date to be determined/II |
| | Femara® | letrozole | Breast cancer (adjuvant therapy) | 2005/III |
| | Zometa® | zoledronate | Treatment of bone metastases | US approved/EU Filed |
| | | | Bone metastases prevention | 2005/III |
| | OctreoTher™ | — | Somatostatin receptor positive tumors | 2004/II |
| | EPO906 | — | Solid tumors | 2004/II |
| | ICL670 | — | Chronic iron overload | 2004/II |
| | PKI166 | — | Solid tumors | 2004/II |
| | PTK787 | — | Solid tumors | 2004/II |
| Central nervous system | Ritalin® LA | methylphenidate | Attention deficit disorders | Filed |
| | Clozaril® (InterSePT) | clozapine | Suicide prevention | 2002/III |
| | Iloperidone | iloperidone | Schizophrenia | 2003/III |
| | Exelon® | rivestigmine | Non-Alzheimer's dementia | 2005/III |
| | Exelon® TDS | rivestigmine | Alzheimer's disease | 2004/II |
| | Trileptal® NP | oxcarbazepine | Neuropathic pain | 2004/II |
| | AMP397 | — | Epilepsy | >2005/II |
| | TCH346 | — | Parkinson's disease, amyotrophic lateral sclerosis | >2005/II |
| Transplantation, immunology | Certican® | everolimus | Transplantation | 2002/III |
| | Myfortic™ (ERL080) | mycophenolate soldium | Transplantation | 2002 (United States III)/EU Filed |
| | FTY720 | — | Transplantation | 2005/II |
| Dermatology | Elidel® oral | pimecrolimus | Inflammatory skin diseases | 2005/II |
| | Elidel® Cream | pimecrolimus | Inflammatory skin diseases | US approved/EU Filed |
| | Lamisil® | terbinafine | Tinea capitis | 2004/III |
| Respiratory | DNK333 | — | Rhinitis, asthma, chronic obstructive pulmonary disease | >2005/II |
| | Foradil® | formoterol | Multi dose dry powder inhaler in asthma | 2003/III |
| | | | "On demand" use (prn) | >2005/III |
| | Xolair® | omalizumab | Asthma/prevention of seasonal allergic rhinitis | Filed |

(1) Phase II: Clinical trials in patients to determine dose ranging, safety and efficacy. Phase III: Large clinical trials to determine definitive safety and efficacy in patients.

| Therapeutic area | Project/ Compound | Generic name | Indication | Estimated Filing Date/Phase[1] |
|---|---|---|---|---|
| Rheuma, bone and hormone replacement therapy | COX189 | — | Rheumatoid arthritis, osteoarthritis, pain | 2002/III |
| | Zoledronic acid | zoledronate | Post-menopausal osteoporosis | >2005/III |
| | | | Paget's disease | 2005/III |
| Ophthalmics | Visudyne™ | verteporfin | Age-related macular degeneration (occult) | 2004/III |
| | | | Age-related macular degeneration (classic) | 2002/III Japan |
| | | | Age-related macular degeneration (minimally classic) | >2005/II |
| | Rescula™ | unoprostone isopropyl | Glaucoma | EU Filed |
| | PKC412 | — | Diabetic macular edema | >2005/II |

(1) Phase II: Clinical trials in patients to determine dose ranging, safety and efficacy. Phase III: Large clinical trials to determine definitive safety and efficacy in patients.

The tables shown above and the summary that follows describe each of our Pharmaceuticals sector's eight key therapeutic areas. Unless otherwise indicated, and subject to required regulatory approvals and, in certain instances, contractual limitations, the intention is to sell the key marketed products throughout the world. These same compounds are in various stages of development throughout the world. For some compounds, the development process is ahead in the United States, whereas for other compounds, development is behind in the United States. Due to regulatory restrictions in some countries, including the United States, it may not be possible to obtain registration of compounds in development for all indications referred to in this annual report.

*Cardiovascular/Metabolism/Endocrinology*

Our Pharmaceuticals sector markets a wide range of products for the treatment of cardiovascular disease, including products for the treatment of hypertension, hyperlipidemia, angina pectoris, heart failure and Type-II diabetes. Ongoing research is focused on the development of innovative new agents to treat metabolic disorders, such as Type-II diabetes, which are associated with serious cardiovascular sequelae including peripheral vascular disease, diabetic retinopathy, nephropathy, stroke and myocardial infarction.

**Recently launched products**

- Starlix® (nateglinide) is a member of a new class of drugs for the treatment of patients with Type-II diabetes, also known as adult-onset diabetes, which affects approximately 6% of the developed world's population, many of whom are presently undiagnosed. We licensed the compound from Ajinomoto Co., Ltd. and own marketing rights for the drug worldwide, except for Japan and several other Asian markets. Starlix® is derived from an amino acid, the basic building block of proteins, and is chemically and pharmacologically distinct from other oral hypoglycemic agents, such as glitazones. The drug aims to restore the early phase of insulin release which helps control blood glucose levels at mealtime. Starlix® is currently being sold in the United States, the EU and other countries.
- Zelmac®/Zelnorm™ (tegaserod/tegaserod maleate) is a 5-$HT_4$ partial agonist developed to address the need for a well-tolerated and effective treatment of irritable bowel syndrome, relieving such symptoms as abdominal pain, constipation and bloating. Switzerland's Swissmedic regulatory

authority has approved Zelmac®, as have the authorities in Mexico, Australia, Venezuela, Argentina, Colombia, the Czech Republic and approximately 19 other nations. The compound is currently in the registration phase in the United States where its name has been changed to Zelnorm™ due to FDA nomenclature confusion concerns.

**Key marketed products**

- Diovan® (valsartan) and Co-Diovan® (valsartan+HCTZ) are early entrants in a new class of antihypertensive agents, the angiotensin II receptor blockers (ARBs). The ARBs are forecast to be a key growth class of drugs within the antihypertensive market. The fixed combination product, Co-Diovan®, provides additional antihypertensive efficacy for patients who require a greater reduction in blood pressure than can be achieved with monotherapy.
- Lescol® (fluvastatin) is a lipid-lowering drug (statin) indicated for the treatment of hyperlipidemia. In addition, Lescol® has been approved in the United States to be marketed for slowing the progression of coronary atherosclerosis in patients with primary hyperlipidemia (including mild forms) and congestive heart failure. Hyperlipidemia is forecast to continue to be a major growth segment in the cardiovascular market.
- Lotrel® (benazepril-amlodipine) is a fixed combination of the ACE-inhibitor benazepril and a leading calcium antagonist (amlodipine). It is marketed only in the United States.
- Cibacen®/Lotensin® (benazepril) and Cibadrex®/Lotensin HCT® (benazepril+HCTZ) are ACE-inhibitors indicated for the first-line treatment of hypertension and as adjunct therapy in heart failure.

**Compounds in development**

- SPP100 is a renin inhibitor being developed for the treatment of hypertension and other cardiovascular indications. Blood pressure lowering effects have been demonstrated in phase II trials, with no significant adverse events observed. The compound is out-licensed to Speedel with a call-back option for us.
- LAF237 is a DPP-IV inhibitor in phase II development for the treatment of type II diabetes. Blocking the action of the enzyme DPP-IV has been shown to improve glycemic control by increasing GLP-1 levels (a peptide that augments glucose-induced insulin secretion and also affects other aspects of glycemic control). Phase I studies have shown that once-a-day dosing maintains DPP-IV activity below the levels believed to be needed to increase GLP-1 activity sufficiently for a therapeutic effect.
- Zelmac®/Zelnorm™ (tegaserod) is in development for irritable bowel syndrome (phase III), chronic constipation (phase III), functional dyspepsia (phase II) and gastroesophagal reflux disease (phase II). In July 2001, the US FDA issued a non-approvable letter, despite giving earlier indications that the drug was approvable. Novartis Pharmaceuticals has filed an appeal with the FDA. In Europe, the file was withdrawn and discussions are ongoing with European Medical Evaluations Agency ("EMEA"). A strategic alliance with Bristol-Myers Squibb Company for the co-development and co-promotion of tegaserod was terminated during 2001.
- Diovan® (valsartan) is in development for congestive heart failure (filed) and post and pre-myocardial infarction (phase III). Diovan® is the only angiotensin II receptor blocker (ARB) with clinical benefits in heart failure to be demonstrated in a large scale trial.
- Sandostatin® LAR (octreotide acetate) is in development for diabetic retinopathy (phase III). This condition affects approximately 15% of patients with diabetes and is one of the leading causes of blindness in people of working age. Currently there are no effective drugs available to treat diabetic retinopathy.
- Lotrel® (benazepril & amlodipine) has two new dosages under development for hypertension (Lotrel® 10-20 and Lotrel®10-40).

- NKS104 (pitavastatin) is a lipid-lowering agent, in development for the treatment of dyslipidemia. We acquired the European marketing rights to pitavastatin in 2001. Clinical trials to date have shown that NKS104 lowers LDL cholesterol and triglycerides while increasing HDL cholesterol levels. The compound is in phase II.
- Starlix® (nateglinide) is currently under development in combination with metformin for Type-II diabetes (phase II).
- Starlix®/Diovan® Navigator (Nateglinide and Valsartan in Impaired Glucose Tolerance and Outcomes Research) trial was initiated in November 2001. 7,500 patients aged 50 years or older will be treated with Diovan® and/or Starlix® to examine the effect on progression from Impaired Glucose Tolerance to type II diabetes after 3 years. Initial results are expected to be available by June 2006.

***Oncology and Hematology***

The Oncology and Hematology disease area is a rapidly growing and increasingly important specialty segment. We market products for the treatment of a number of different cancers and for metastatic bone disease. Research and development in this disease area is aimed at the discovery and development of innovative approaches to the treatment of cancer, focusing in particular on the major forms of solid tumors (lung, breast, prostate and colorectal cancer), which account for approximately 50% of all deaths from cancer. In addition, compounds are being developed for the treatment of other forms of cancer including glioblastoma, melanoma, ovarian cancer, leukemia, lymphoma and sarcoma.

**Recently launched products**

- Glivec®/Gleevec™ (imatinib mesylate) is a signal transduction inhibitor being developed to treat several forms and phases of chronic myeloid leukemia (CML). It has achieved an unprecedented level of efficacy in both the chronic and the advanced phases of CML, and was approved in record time by the FDA for Interferon-intolerant and resistant patients. It gained approval in all key markets during 2001 (United States, EU, Japan). The compound is widely seen as a new model for rational drug development, leading to high efficacy and relatively low toxicity, as it specifically targets the genetic cause of the disease. Glivec®/Gleevec™ was approved in February 2002 in the United States for the treatment of inoperable gastrointestinal stromal tumors (GIST) and has been filed in Europe for the same indication. In addition, the potential of Glivec®/Gleevec™ is being studied in solid tumors as a basis for widening the range of indications to include other types of cancer.
- Zometa® (zoledronate) is a more potent bisphosphonate than Aredia®, and is being developed to offer patients a more advanced alternative treatment. It has recently been launched in key markets in its first indication "hypercalcemia of malignancy." In February 2002, Zometa® received approval from the FDA for the treatment of multiple myeloma and bone metastases from a broad range of tumors including prostate cancer, a tumor type in which other bisphosphonates could not demonstrate clear efficacy to date.

**Key Marketed Products**

- Aredia® (pamidronate) is a therapy for tumor-induced hypercalcemia, osteolysis from multiple myeloma and bone metastases from breast cancer. Our patent protection for Aredia® is limited. A generic version of Aredia® was launched in the United States in 2001. Others have been tentatively approved by the FDA and are expected to be launched in May of 2002. Generic products in competition with Aredia® are on sale in Canada and elsewhere.
- Femara® (letrozole) is an oral aromatase inhibitor for the treatment of advanced breast cancer in women with natural or artificially induced post-menopausal status. It recently received approval for

first-line therapy globally, based upon superior efficacy over the most widely used previous standard therapy, tamoxifen. It also is being developed for adjuvant therapy of breast cancer.

- Sandostatin® (octreotide) is a synthetic octapeptide derivative of the hormone somatostatin indicated for the treatment of pancreatic and gastrointestinal endocrine tumors, acromegaly, and acute variceal bleeding. Patent protection or regulatory exclusivity will expire in the next five years in major markets for this product. The basic octreotide substance patents expire in 2002 in the United States and Japan, and from 2003 and 2009 in major EU countries. However, protection extending to 2010 (and 2013 and beyond in the United States) continues in major markets for Sandostatin® LAR, which represents a significant and growing proportion of our Pharmaceuticals sector's octreotide sales.
- Sandostatin® LAR (octreotide) is a depot injection used for the treatment of acromegaly. In addition, this long-acting release formulation is approved for the control of symptoms such as the severe diarrhea and flushing associated with metastatic carcinoid tumors, and the severe diarrhea associated with vasoactive intestinal polypeptide secreting tumors.

**Compounds in Development**

- Glivec®/Gleevec™ (imatinib mesylate) is being studied in several solid tumors as a basis for widening the range of indications to include other types of cancers. Phase II trials are in progress.
- Femara® (letrozole) is in phase III development for adjuvant therapy in the treatment of breast cancer.
- Zometa® (zoledronate) is also in phase III development for the prevention of bone metastases.
- OctreoTher™ is in phase II trials for the treatment of somatostatin receptor positive tumors.
- EPO906 (epothilone B), a novel tubulin polymerizing compound, is a cytotoxic with a similar mechanism of action as Taxol® (paclitaxel). The taxane segment is the largest cytotoxic market segment in oncology. Preclinically, Epothilone B has shown more potency than paclitaxel and more activity in paclitaxel resistant tumors. Responses have been observed in phase I in several solid tumors and it is now in phase II clinical development. Dose limiting toxicity is diarrhea. Significant myelosupression has not been reported to date.
- ICL670 is an iron chelator currently in phase II clinical development. It was designed to enhance patient acceptance and was selected from over 700 compounds of 6 chemical classes tested. Iron accumulation resulting from red blood cell lysis can lead to organ damage and, ultimately, death. ICL670 has been shown preclinically to efficiently induce iron excretion. Bioavailability has been demonstrated orally. Recently published clinical data (American Society of Hematology 2001) demonstrate clinical effectiveness of ICL670 in achieving negative iron balance. The goal is to make iron chelation therapy more practical for patients with chronic iron overload.
- PKI166 is a tyrosine kinase inhibitor that targets the epidermal growth factor receptor (EGF-r). Over expression of the EGF-r has been demonstrated in a number of human cancers, including breast, non-small cell lung, prostate, head and neck as well as ovarian cancers. Preclinical studies with PKI166 have shown that cellular proliferation and tumor growth can be inhibited in a wide variety of human tumor types, either used alone or in combination with other anti-cancer agents. PKI166 is a new chemical entity belonging to the pyrrolo-pyrimidine class of compounds. It is currently in phase II development.
- PTK787 is a new chemical entity with a novel mechanism of action, which inhibits tumor growth and the development of metastases through inhibition of tumor vascularization. It is expected to be biologically effective as an oral anti-angiogenic agent, in particular in combination with standard therapies against a broad range of tumor types. No significant toxicities are expected at efficacious doses that would preclude chronic administration. PTK787 is in phase I/II development, and has shown no significant toxicity to date. The compound is being developed in collaboration with Schering AG, Germany.

*Central Nervous System*

Novartis Pharmaceuticals markets a broad range of central nervous system products, including agents to treat patients with schizophrenia, epilepsy, Parkinson's disease, Alzheimer's disease, attention deficit hyperactivity disorder and migraine headaches. Ongoing research to extend the current product portfolio in this disease area includes projects in psychiatric disease (psychoses, depression, and anxiety), neurological disorders (epilepsy, Parkinson's disease, and Alzheimer's disease), learning disorders and chronic pain.

**Key marketed products**

- Exelon® (rivastigmine) is a therapy for the treatment of patients with mild to moderate Alzheimer's disease. Exelon® has been approved in all major markets, including the 15 member-states of the EU and the United States.
- Leponex®/Clozaril® (clozapine) is a neuroleptic agent used in treatment-resistant schizophrenia and is experiencing competition from generic competitors in many markets, including the United States.
- Tegretol® (carbamazepine) was launched in 1963 for the treatment of epileptic seizures and remains a mainstay in the treatment of the disorder.
- Trileptal® (oxcarbazepine) is an anti-epileptic drug for the treatment of partial seizures as adjunctive or monotherapy in adults, or as adjunctive therapy in children.
- Comtan® (entacapone) treats Parkinson's disease by enhancing the action of levodopa, the standard therapy for Parkinson's disease. The compound is licensed from Orion Pharma of Finland.

**Compounds in development**

- Ritalin® LA (methylphenidate) is currently in registration in the United States and the EU for the treatment of Attention Deficity Hyperactivity Disorder (ADHD).
- Clozaril® (clozapine) is currently in phase III development (InterSePT trial) for the prevention of suicide in schizophrenia.
- Iloperidone is a mixed serotonin/dopamine antagonist for the treatment of schizophrenia and other related psychotic disorders. Iloperidone is licensed from Titan Pharmaceuticals, Inc. and is currently in phase III clinical trials.
- Exelon® (rivastigmine) is also in development for additional indications and formulations. Exelon® is being investigated in phase III trials for the treatment of non-Alzheimer's dementias. A transdermal formulation, Exelon® TDS, is in phase II development for Alzheimer's disease.
- Trileptal® (oxcarbazepine) is in phase II development for the treatment of diabetic neuropathic pain.
- AMP397 is in phase II development for the treatment of epilepsy.
- TCH346 is in phase II development for the treatment of Parkinson's disease and Amyotrophic Lateral Sclerosis (ALS).

*Transplantation/Immunology*

We are a leader in the development of transplantation medicine, producing widely used products that help to prevent the rejection of organs following transplantation. A wide-ranging research and development program is aimed at developing new compounds and interventions in the area of chronic rejection, tolerance induction, Beta-cell inhibition, ischemia/reperfusion injury to reduce delayed graft function, inhaled therapies for lung transplantation and pancreatic islet transplantation.